AMENDMENTS TO THE SPECIFICATION

Please insert the following new paragraph at page 2, line 20.

-- Thus, it is the object of the present invention to provide a simple, inexpensive device which is intended to be injected or inserted into the needle biopsy site at the termination of the procedure and which will serve as a temporary marker for subsequent surgery, and, in most cases, obviate the need for the needle localization procedure. The device would allow the surgeon to visually and tactilely locate the previously biopsied site. It is also an object of the present invention that the device be biodegradable and resorbable, allowing the device to gradually vanish in women with benign diagnoses, obviating the unneeded permanent metallic marker in the great majority of women undergoing breast biopsies. –

Please replace the paragraph extending from page 2, line 33 – page 3, line 17 with the following paragraph.

-- One preferred material used as the bioabsorbable element is a dehydrated collagen plug. This type of plug may swell and is palpable for subsequent location by the surgeon. The collagen plug may not swell at all. In some situations, such as with small breasted women or where the biopsy site is close to the surface, a non-swellable bioabsorbable material, such as a round pellet of PGA, can be used instead of a swellable bioabsorbable material. The bioabsorbable material can also be made so that it is absorbed quickly to produce a local tissue inflammation; such a localized inflammation can be used to locate the biopsy site instead of location by palpation. Instead of leaving, for example, a collagen plug, a PGA pellet or a bioabsorbable suture material at the biopsy

site for location by palpation or inflammation, a length of bioabsorbable suture material, a collagen filament, or other bioabsorbable material extending from the biopsy site out through the skin can be used. In this case the surgeon can follow the bioabsorbable suture material to the biopsy site in a manner similar to that used with Hawkins needles. It may be advantageous to enhance the visual detectability of the device by coloring it or causing it to contain a bioresorbable color such as methylene blue or other dye. This could be accomplished by one of several known methods. In other cases, such as in the case of a deeply located lesion or large breast, the bioabsorbable material may need to be located by the radiologist, by for example, ultrasound, x-ray, MRI, or mammography. In the case of ultrasound, most any material would have reflective properties different than the surrounding breast tissue and be detectable. For the device to be detected by mammography, it would have to be radiopaque and probably contain iodine or other radiopaque material (re-sorbable or not re-sorbable). In any event the bioabsorbable material will typically be absorbed within about a month of placement. The invention thus eliminates the use of metal clips during biopsies and usually eliminates the need for return to the radiologist for preoperative localization. –

Please insert the following new paragraph after page 3, line 17.

-- Because the device is bioresorbable and biodegradable, the device will be of obvious advantage to those patients with benign diagnoses. However, the device must not be resorbed so quickly that it is not palpable at the time of surgical wide excision in the case of a malignant diagnosis. Typically, the pathologic diagnosis is available within 24-48 hours after the biopsy. The

patient is then informed of the results, and if malignant, arrangements are made for surgical consultation. The patient usually is seen by the surgeon with a week and the surgery is completed within the next week. Therefore, the device must not be significantly resorbed for at least two weeks after it is deployed or implanted within the breast. There is a relative dilemma in that the device must be resorbed quickly enough to cause no discomfort, but must not be resorbed until the patient with the malignant diagnosis has the necessary wide excisional surgery. --

Please insert the following new paragraph after page 6, line 1.

-- The subject medical device may be made of a substance which is bioresorbable and is of a consistency and size which can be palpated days to weeks after it is deployed within the soft tissues of the body. The size or consistency may be different in the deployed and non-deployed state. It may be injectable or implantable through a needle or other delivery device. --

Please insert the following new paragraph after page 7, line 2.

-- A preferred bioresorbable substance may be bovine collagen, which may be shaped into a small cylinder and inserted through a needle into the biopsy site where blood and other body fluids will cause it to swell and enlarge to a size which cause it to be palpable. It would remain palpable for several weeks and then be resorbed, if not removed surgically in the interim.

Collagen will tend to expand upon contact with body fluids, and there is frequently blood within the lumen of the biopsy needle, delivery device, and biopsy cavity. Blood will likely collect in these areas before the marker device could be inserted even if blood is aspirated immediately prior to insertion. Therefore, a method of isolating the collagen or other substance from the blood, and preventing these substances from swelling until being deposited in the biopsy site, is anticipated. One solution is to cover all or a portion of the marker device with a thing layer or film of bioresoble material which does not immediately react with or absorb blood or body fluids. --

Please replace the paragraph on page 7, lines 3-15 with the following.

-- A bioabsorbable element could be made of materials other than collagen and could be in a form other than a solid, relatively hard plug in its pre-delivery state. For example, bioabsorbable element 34 in its pre-delivery state within barrel 30 could be in a liquid or otherwise flowable form; after being deposited at open region 26 at target site 18, the bioabsorbable element could change to become palpably harder than the surrounding tissue 36 to permit subsequent relocation of target site 18 by palpation. <u>It may be advantageous to enhance the visual detectability of the device by coloring it or causing it to contain a bioresorbable color such as methylene blue or other dye.</u> In some situations, it may be desired that bioabsorbable element 34 not change its size or hardness between its pre-delivery state and its post-delivery state, such as being palpably harder than the surrounding tissue 36 in both states. In a preferred embodiment, transformation of bioabsorbable element 34 is by contact with an aqueous liquid. However, transformation of the bioabsorbable element, which can be in terms of, for example, hardness, texture, shape, size, or a combination

thereof, can be due to other factors, such as application of thermal energy, radiation, magnetic energy, etc. --

Please insert the following paragraph after page 7, line 15.

-- Because some materials may react with blood or other fluids before being completely deployed, a thin coating of a second material may be needed to permit the device to be completely deployed. It is anticipated that the second material would be rather quickly biodegradable, which would allow the first material to expand or react with body fluids after deployment. --